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JUL 0 6 200 PTO/SB/21 (08-03) Approved for use through 08/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE ct of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Paperwork R Application Number 09/254.617 **TRANSMITTAL** Filing Date March 22, 1999 FORM First Named Inventor Jacques MALLET, et al. Art Unit 1632 (to be used for all correspondence after initial filing) Certificate Examiner Name Anne-Marie Falk Attorney Docket Number ST96025-US Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication Fee Transmittal Form Drawing(s) to Technology Center (TC) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition Amendment/Reply (Appeal Notice, Brief, Reply Brief) Petition to Convert to a Proprietary Information After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Extension of Time Request Terminal Disclaimer Identify below): Request for Cert. of Correction (1 pg); Cert. Request for Refund **Express Abandonment Request** of Correction Form (1 page); copy of pages 1-7 from Amendment After Final (7 pages). CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Customer No. 29693 Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm David J. Kulik, Reg. No. 36,576 Individual name Signature Date July 6, 2004 CERTIFICATE OF TRANSMISSION/MAILING

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PATENT

Attorney Docket No.: ST96025-US

### N THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jacques MALLET, et al.

Patent. No.: 6,723,315 B1 (Issued April 20, 2004)

Application No. 09/254,617

For:

METHOD FOR TREATING

AMYOTROPHIC LATERAL SCLEROSIS

Group Art Unit: 1632

Examiner: Anne-Marie Falk

## REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322(a)

Certificate of Correction Branch Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants respectfully request a Certificate of Correction under 37 CFR 1.322(a) be entered in the above-identified patent. This request is being submitted to correct errors in the issued patent referenced above, as enumerated on the attached Certificate of Correction Form PTO/SB/44. We also attach copies of pages 1-7 from the Amendment After Final filed on October 2, 2003, providing the amended listing of claims to replace all prior versions of claims in this application. It is evident from the attached listing of claims that the errors in the issued patent arose through the fault of the Patent Office. Accordingly, Applicant does not believe any fees are required to process this request. However, in the event any fees are due or required, please charge the undersigned's Deposit Account No. 50-1129.

Respectfully submitted,

WILEY REIN & FIELDING LLP

Date: July 6, 2004

By:

David J. Kulik, Reg. No. 36,576

WILEY REIN & FIELDING LLP

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JUL 1 2 2004

## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO

6,723,315 B1

DATED

April 20, 2004

INVENTOR(S):

Jacques MALLET, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

#### In the claims:

Claim 5, line 53, change "adenoviruses adenovirus" to --adenovirus--.

Claim 10, line 1, change "according to" to --of--.

Claim 17, line 27, change "a cassette" to --cassette--.

Claim 24, line 60, change "of transcriptional" to -- of a transcriptional--.

Claim 29, line 4, change "comprises an a" to --comprises a--.

Claim 49, line 55, change "factors" to --factor--.

Claim 50, line 59, change "factor under the" to --factor.--.

Claim 55, line 2, change "factors" to --factor--.

Claim 56, line 4, change "factors" to --factor--.

Claim 57, line 6, change "factors" to --factor--.

Claim 58, line 8, change "factors" to --factor--.

PATENT NO. 6,723,315 B1

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MAILING ADDRESS OF SENDER: WILEY REIN & FIELDING, LLP DAVID J. KULIK, REG. NO. 36,576 ATTN: PATENT ADMINISTRATION 1776 K STREET, NW

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.

09/254,617

Confirmation No. 7283

**Applicant** 

Jacques MALLET

Filed

March 22, 1999

TC/A.U.

1632

Examiner

Anne Falk

Docket No.

ST96025-US

Customer No.

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### **AMENDMENT AFTER FINAL**

Sir:

In response to the Final Office Action of January 28, 2003 (Paper No. 20), and the Advisory Action of September 10, 2003 (Paper No. 25), applicants request reconsideration. In addition, in order to place the application in better form for appeal or in condition for allowance, applicants request entry of the following amendments. Applicants previously filed a Notice of Appeal on July 28, 2003; therefore this response is timely filed.

Appl. No. 09/254,617 Amdt. After Final dated October 2, 2003 Reply to Advisory Action of September 10, 2003

#### Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

#### **Listing of Claims:**

Claims 1-63 canceled.

- 64. (previously presented) A pharmaceutical composition comprising two adenovirus vectors, wherein each vector comprises a nucleic acid encoding a different neurotrophic factor.
- 65. (currently amended) The pharmaceutical composition according to claim 64, wherein the vectors comprise an expression cassette for the simultaneous expression of two different neurotrophic factors having the coding sequences of two different neurotrophic factors and having sequences that provide for the simultaneous expression of the two different neurotrophic factors.
- 66. (previously presented) The pharmaceutical composition according to claim 64, wherein the neurotrophic factors are selected from GDNF, BDNF, CNTF and NT3.
- 67. (currently amended) The pharmaceutical composition according to claim 66, wherein the adenovirus vectors are two replication defective recombinant adenoviruses adenovirus vectors, and wherein one adenovirus vector comprises a nucleic acid encoding CNTF and one adenovirus vector comprises a nucleic acid encoding GDNF.
- 68. (currently amended) The pharmaceutical composition according to claim 66, wherein the adenovirus vectors are two replication defective recombinant adenoviruses adenovirus vectors, and wherein one adenovirus vector comprises a nucleic acid encoding GDNF and one adenovirus vector comprises a nucleic acid encoding NT3.
- 69. (currently amended) The pharmaceutical composition according to claim 66, wherein the adenovirus vectors are two replication defective recombinant adenoviruses adenovirus vectors, and wherein one adenovirus vector comprises a nucleic acid encoding BDNF and one adenovirus vector comprises a nucleic acid encoding NT3.
- 70. (previously presented) The pharmaceutical composition according to claim 64, in an injectable form.

- 71. (previously presented) The pharmaceutical composition according to claim 64, further comprising riluzole.
- 72. (previously presented) The pharmaceutical composition according to claim 71, in an injectable form.
- 73. (previously presented) The pharmaceutical composition of claim 64, wherein one of the neurotrophic factors is CNTF.
- 74. (previously presented) The pharmaceutical composition of claim 64, wherein one of the neurotrophic factors is BDNF.
- 75. (previously presented) The pharmaceutical composition of claim 64, wherein at least one adenovirus vector is a replication defective recombinant adenovirus vector.
- 76. (previously presented) A method of treating amyotrophic lateral sclerosis comprising administering to a subject by systemic administration a pharmaceutical composition comprising an adenovirus vector comprising a nucleic acid encoding a neurotrophic factor, wherein the treatment results in a reduction in progressive motor neuron degeneration in said subject.
- 77. (previously presented) A method of treating amyotrophic lateral sclerosis comprising administering to a subject by systemic administration a pharmaceutical composition comprising an adenovirus vector comprising a nucleic acid encoding a neurotrophic factor, wherein the treatment results in a reduction in progressive denervation in said subject.
- 78. (previously presented) The method of claim 76, wherein the reduction in progressive motor neuron degeneration is detectable by a change in the rate of loss of the number of myelinized fibers in a peripheral nervous tissue.
- 79. (previously presented) The method of claim 77, wherein the reduction in progressive denervation is detectable by electromyography.
- 80. (previously presented) The method of claim 76, wherein the adenovirus vector comprises an expression cassette comprising a nucleic acid encoding a neurotrophic factor under the control of a transcriptional promoter.
- 81. (previously presented) The method of claim 77, wherein the adenovirus vector comprises an expression cassette comprising a nucleic acid encoding a neurotrophic factor under the control of a transcriptional promoter.

- 82. (previously presented) The method of claim 78, wherein the adenovirus vector comprises an expression cassette comprising a nucleic acid encoding a neurotrophic factor under the control of a transcriptional promoter.
- 83. (previously presented) The method of claim 79, wherein the adenovirus vector comprises an expression cassette comprising a nucleic acid encoding a neurotrophic factor under the control of a transcriptional promoter.
- 84. (previously presented) The method of claim 76, wherein the adenovirus vector comprises two expression cassettes, wherein each cassette comprises a nucleic acid encoding a different neurotrophic factor under the control of a transcriptional promoter.
- 85. (previously presented) The method of claim 77, wherein the adenovirus vector comprises two expression cassettes, wherein each cassette comprises a nucleic acid encoding a different neurotrophic factor under the control of a transcriptional promoter.
- 86. (previously presented) The method of claim 78, wherein the adenovirus vector comprises two expression cassettes, wherein each cassette comprises a nucleic acid encoding a different neurotrophic factor under the control of a transcriptional promoter.
- 87. (previously presented) The method of claim 79, wherein the adenovirus vector comprises two expression cassettes, wherein each cassette comprises a nucleic acid encoding a different neurotrophic factor under the control of a transcriptional promoter.
- 88. (previously presented) The method of claim 76, wherein the neurotrophic factor is GDNF, CNTF, BDNF or NT3.
- 89. (previously presented) The method of claim 77, wherein the neurotrophic factor is GDNF, CNTF, BDNF or NT3.
- 90. (previously presented) The method of claim 78, wherein the neurotrophic factor is GDNF, CNTF, BDNF or NT3.
- 91. (previously presented) The method of claim 79, wherein the neurotrophic factor is GDNF, CNTF, BDNF or NT3.
- 92. (currently amended) The method of claim 76, wherein the adenovirus vector comprises an <u>a bicistronic</u> expression cassette comprising two nucleic acid sequences, wherein each nucleic acid sequence encodes a different neurotrophic factor <del>under the control of a single transcriptional promoter</del>.

- 93. (previously presented) The method of claim 92, wherein the neurotrophic factors are selected from GDNF, CNTF, BDNF and NT3.
- 94. (previously presented) The method of claim 93, wherein the neurotrophic factors are CNTF and GDNF.
- 95. (currently amended) The method of claim 92, wherein the <u>bicistronic expression</u> cassette further comprises a transcriptional promoter, the promoter selected from a constitutive eucaryotic <u>promoter</u> or <u>a</u> viral promoter.
- 96. (previously presented) The method of claim 95, wherein the promoter is selected from a CMV, RSV, or adenovirus promoter.
- 97. (previously presented) The method of claim 76, wherein the systemic administration comprises intravenous administration.
- 98. (previously presented) The method of claim 77, wherein the systemic administration comprises intravenous administration.
- 99. (previously presented) The method of claim 78, wherein the systemic administration comprises intravenous administration.
- 100. (previously presented) The method of claim 79, wherein the systemic administration comprises intravenous administration.
- 101. (previously presented) The method of claim 76, further comprising administering riluzole.
- 102. (previously presented) The method of claim 77, further comprising administering riluzole.
- 103. (previously presented) The method of claim 78, further comprising administering riluzole.
- 104. (previously presented) The method of claim 79, further comprising administering riluzole.
- 105. (previously presented) The method of claim 84, further comprising administering riluzole.
- 106. (previously presented) The method of claim 85, further comprising administering riluzole.
- 107. (previously presented) The method of claim 88, further comprising administering riluzole.

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- 108. (previously presented) The method of claim 89, further comprising administering riluzole.
- 109. (previously presented) A method of treating amyotrophic lateral sclerosis comprising administering to a subject by systemic administration a pharmaceutical composition comprising an adenovirus vector comprising a nucleic acid encoding a neurotrophic factor, wherein the treatment results in increased lifespan for said subject.
- 110. (previously presented) The method of claim 109, wherein the adenovirus vector comprises an expression cassette comprising a nucleic acid encoding a neurotrophic factor under the control of a transcriptional promoter.
- 111. (previously presented) The method claim 109, wherein the adenovirus vector comprises two expression cassettes, wherein each cassette comprises a nucleic acid encoding a different neurotrophic factor under the control of a transcriptional promoter.
- 112. (previously presented) The method of claim 109, wherein the neurotrophic factor is one of GDNF, CNTF, BDNF or NT3.
- 113. (currently amended) The method of claim 109, wherein the adenovirus vector comprises an <u>a bicistronic</u> expression cassette comprising two nucleic acid sequences, wherein each nucleic acid sequence encodes a different neurotrophic factor under the control of a single transcriptional promoter.
- 114. (previously presented) The method of claim 111, wherein the neurotrophic factors are selected from GDNF, CNTF, BDNF and NT3.
- 115. (previously presented) The method of claim 111, wherein the neurotrophic factors are CNTF and GDNF.
- 116. (previously presented) The method of claim 110, wherein the transcriptional promoter is a constitutive eucaryotic or viral promoter.
- 117. (previously presented) The method of claim 116, wherein the promoter is selected from a CMV.

RSV, or adenovirus promoter.

- 118. (previously presented) The method of claim 109, wherein the neurotrophic factor is CNTF.
- 119. (previously presented) The method of claim 109, wherein the neurotrophic factor is GDNF.

- 120. (previously presented) The method of claim 109, wherein the neurotrophic factor is BDTF
- 121. (previously presented) The method of claim 109, wherein the neurotrophic factor is NT3.
- 122. (previously presented) The method of claim 109, further comprising administering riluzole.
- 123. (previously presented) The method of claim 111, further comprising administering riluzole.
- i24. (previously presented) The method of claim 112, further comprising administering riluzole.
- 125. (previously presented) The method of claim 109, wherein the systemic administration comprises intravenous administration.
- 126. (previously presented) The method of claim 111, wherein the systemic administration comprises intravenous administration.
- 127. (previously presented) The method of claim 112, wherein the systemic administration comprises intravenous administration.
- 128. (previously presented) The method of claim 122, wherein the systemic administration comprises intravenous administration.